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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/826,149      | 04/16/2004  | Michael A. Spohn     | CV/04-002           | 8770             |

21140 7590 05/22/2009  
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| EXAMINER |
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GILBERT, ANDREW M

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| ART UNIT | PAPER NUMBER |
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3767

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05/22/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/826,149 | <b>Applicant(s)</b><br>SPOHN ET AL. |  |
|                              | <b>Examiner</b><br>ANDREW M. GILBERT | <b>Art Unit</b><br>3767             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 42,55,56,58,60,70-73 and 75-77 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42,55,56,58,60,70-73 and 75-77 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### ***Acknowledgments***

1. This office action is in response to the reply filed on 2/13/2009.
2. In the reply the Applicant amended claims 42, 60 and added new claims 76-77.
3. Thus, claims 42, 55-56, 58, 60, 70-73, 75-77 are pending for examination.

### ***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 42, 57-60, 72-77 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6866654 in view of Trombley III et al (6096011) in view of Morimoto et al (6224568).
3. Claims 1-9 of US Pat No. 6866654 teaches that it is known to have a pressure isolation mechanism having a lumen, a pressure isolation port, a pressure transducer,

and a valve member biased to a normally open position permitting fluid communication between the lumen and the pressure isolation port and movable to a closed position when the fluid pressure in the lumen reaches a predetermined pressure level sufficient to overcome the biasing force of the biasing portion of the valve member and wherein when in the closed position the valve member is adapted to allow fluid communication between the inlet and the outlet of the lumen while preventing fluid communication between the lumen and the pressure isolation port.

4. Trombley, III et al discloses an injector system comprising: a source of injection fluid (505); a pump device (350); a fluid path set (Fig 6A-B) disposed between the source of injection fluid and the pump device, and comprising a first section (420) and a second section (510); and at least one connector (Fig 2-5) providing the removable fluid communication between the first section and the second section, the connector comprising: a first connector member (155) associated with one of the first section and the second section and comprising an outer housing (172) and a first threaded member (172) disposed in the outer housing; and a second connector member (175) associated with the other of the first section and the second section and comprising a second threaded member (192); wherein the first threaded member and second threaded member cooperate to securely and releasably connect the first member to the second member to establish the removable fluid communication between the first section and the second section (Figs 1-6b; col 5, lns 38-45), and wherein the second threaded member is received in the outer housing of the first connector member when the first connector member is connected to the second connector member (Fig 5); as to claims

57-59 and 73-75, see (Fig 6A, B; wherein the drip chamber has a projection, or spike 520; 400; col 6, lns 18-34; and 194 and proximal edge portion of 155 (ie corners closest to reference number 166) in Fig 4). It would be obvious to modify the pressure isolation mechanism of US Pat No 6866654 with a fluid injection system and connector system as taught by Trombley, III et al for the purpose of delivery fluid to a patient.

5. However, Trombley, III et al does not expressly disclosing a connector having a first connector member having an first threaded member separated therefrom by an annular cavity.

6. Morimoto et al teaches that it is known to have a connector (13) having a first connector member (41) having a first threaded member (41, 43) separated therefrom by an annular cavity (41) for the purpose of providing a shield between the sealing members (14, 41) of first and second connectors and the external environment helping to maintain sterility during storage or use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the first connector as taught by Trombley, III et al with the first connector being separated therefrom by an annular cavity as taught by Morimoto et al for the purpose of providing a shield between the sealing members (14, 41) of first and second connectors and the external environment helping to maintain sterility during storage or use. Also, see discussion of Morimoto et al in Final Rejection mailed on 6/13/2008.

7. However, Trombley, III et al and Morimoto et al do not expressly disclose a second section having a pressure isolation mechanism having a lumen, a pressure isolation port, and a valve member biased to a normally open position permitting fluid

communication between the lumen and the pressure isolation port and movable to a closed position when the fluid pressure in the lumen reaches a predetermined pressure level sufficient to overcome the biasing force of the biasing portion of the valve member; wherein when in the closed position the valve member is adapted to allow fluid communication between the inlet and the outlet of the lumen while preventing fluid communication between the lumen and the pressure isolation port.

4. Claims 55-56 and 70-71 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6866654 in view of Trombley III et al (6096011) in view of Morimoto et al (6224568) and in further view of Raines et al (5618268).

5. Trombley, III et al and Morimoto et al and US Pat No 6866654 disclose the invention substantially as claimed except for expressly disclosing a cap having a groove associated with a raised rib of at least one of the first and second connector members. Raines et al teaches that it is known to have a cap with a groove (21, 66, 16) for a connector member for the purpose of protecting the infusion port and connector prior to use. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device as taught by Trombley, III et al and Morimoto et al and US Pat No 6866654 with the protective cap as taught by Raines et al for the purpose of protecting the infusion port and connector prior to use.

***Response to Arguments***

1. Applicant's arguments with respect to claims 42, 55-56, 58, 60, 70-73, 75 have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

2. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/  
Examiner, Art Unit 3767

/Nicholas D Lucchesi/  
Supervisory Patent Examiner, Art Unit 3763